EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA); Scientific Opinion on the substantiation of health claims related to policosanols from sugar cane wax and maintenance of normal blood LDL-cholesterol concentrations (ID 1747, 1748, 1864, 1951, 1954, 4693) and maintenance of normal blood HDL-cholesterol concentrations (ID 1747, 1748, 1864, 1951, 1954, 4693) pursuant to Article 13(1) of Regulation (EC) No 1924/2006

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SCIENTIFIC OPINION

Scientific Opinion on the substantiation of health claims related to policosanols from sugar cane wax and maintenance of normal blood LDL-cholesterol concentrations (ID 1747, 1748, 1864, 1951, 1954, 4693) and maintenance of normal blood HDL-cholesterol concentrations (ID 1747, 1748, 1864, 1951, 1954, 4693) pursuant to Article 13(1) of Regulation (EC) No 1924/2006[1]

EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA)[2, 3]

European Food Safety Authority (EFSA), Parma, Italy

SUMMARY

Following a request from the European Commission, the Panel on Dietetic Products, Nutrition and Allergies was asked to provide a scientific opinion on a list of health claims pursuant to Article 13 of Regulation (EC) No 1924/2006. This opinion addresses the scientific substantiation of health claims in relation to policosanols from sugar cane wax and maintenance of normal blood LDL-cholesterol concentrations and maintenance of normal blood HDL-cholesterol concentrations. The scientific substantiation is based on the information provided by the Member States in the consolidated list of Article 13 health claims and references that EFSA has received from Member States or directly from stakeholders.

The food constituent that is the subject of the health claims is policosanols from sugar cane wax. The Panel considers that policosanols from sugar cane wax are sufficiently characterised.

Maintenance of normal blood LDL-cholesterol concentrations

The claimed effects are "cholesterol", "support for healthy blood lipid levels", and "cardiovascular system". The target population is assumed to be the general population. In the context of the proposed wordings, the Panel assumes that the claimed effects refer to the maintenance of normal blood

[1] On request from the European Commission, Question No EFSA-Q-2008-2480, EFSA-Q-2008-2481, EFSA-Q-2008-2597, EFSA-Q-2008-2684, EFSA-Q-2008-2687, EFSA-Q-2010-00646, adopted on 08 April 2011.

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[3] Acknowledgement: The Panel wishes to thank for the preparatory work on this scientific opinion: The members of the Working Group on Claims: Carlo Agostoni, Jean-Louis Bresson, Susan Fairweather-Tait, Albert Flynn, Ines Golly, Marina Heinonen, Hannu Korhonen, Martinus Løvik, Ambroise Martin, Hildegard Przyrembel, Seppo Salminen, Yolanda Sanz, Sean (J.J.) Strain, Inge Tetens, Hendrik van Loveren and Hans Verhagen. The members of the Claims Sub-Working Group on Cardiovascular Health/Oxidative Stress: Antti Aro, Marianne Geleijnse, Marina Heinonen, Ambroise Martin, Wilhelm Stahl and Henk van den Berg.

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LDL-cholesterol concentrations. The Panel considers that maintenance of normal blood LDL-cholesterol concentrations is a beneficial physiological effect.

In weighing the evidence, the Panel took into account that the results from human intervention studies which assessed the effects of policosanols from sugar cane wax on total and LDL-cholesterol concentrations were inconsistent, and that no evidence for a mechanism by which policosanols from sugar cane wax could exert the claimed effect has been provided.

On the basis of the data presented, the Panel concludes that a cause and effect relationship has not been established between the consumption of policosanols from sugar cane wax and maintenance of normal blood LDL-cholesterol concentrations.

Maintenance of normal blood HDL-cholesterol concentrations

The claimed effects are "cholesterol", "support for healthy blood lipid levels", and "cardiovascular system". The target population is assumed to be the general population. In the context of the proposed wordings, the Panel assumes that the claimed effects refer to the maintenance of normal HDL-cholesterol concentrations. The Panel considers that maintenance of normal HDL-cholesterol concentrations (without increasing LDL-cholesterol concentrations) is a beneficial physiological effect.

In weighing the evidence, the Panel took into account that the results from human intervention studies which assessed the effects of policosanols from sugar cane wax on HDL-cholesterol concentrations were inconsistent, and that no evidence for a mechanism by which policosanols from sugar cane wax could exert the claimed effect has been provided.

On the basis of the data presented, the Panel concludes that a cause and effect relationship has not been established between the consumption of policosanols from sugar cane wax and maintenance of normal blood HDL-cholesterol concentrations.

KEY WORDS

Policosanols, sugar cane wax, LDL, HDL, cholesterol, health claims.

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INFORMATION AS PROVIDED IN THE CONSOLIDATED LIST

The consolidated list of health claims pursuant to Article 13 of Regulation (EC) No 1924/2006[4] submitted by Member States contains main entry claims with corresponding conditions of use and literature for similar health claims. EFSA has screened all health claims contained in the original consolidated list of Article 13 health claims which was received by EFSA in 2008 using six criteria established by the NDA Panel to identify claims for which EFSA considered sufficient information had been provided for evaluation and those for which more information or clarification was needed before evaluation could be carried out[5]. The clarifications which were received by EFSA through the screening process have been included in the consolidated list. This additional information will serve as clarification to the originally provided information. The information provided in the consolidated list for the health claims which are the subject of this opinion is tabulated in Appendix C.

ASSESSMENT

1. Characterisation of the food/constituent

The food constituents that are the subject of the health claims are "policosanols", "sugar cane extract" and "policosanol/blend of aliphatic alcohols - consisting primarily of 1-Octacosanol, 1-Triacontanol, 1-Tetracosanol and 1-Hexacosanol - from sugar cane (*Saccharum officinarum*)".

Commercial policosanol preparations are a mixture of long-chain primary alcohols derived from sugar cane wax (*Saccharum officinarum* L.) with chain lengths varying from 24 to 34 carbon atoms. Policosanols can also be derived from a variety of other plant sources, including wheat germ oil, and their composition depends on the source.

From the references provided, the Panel assumes that the food constituent which is the subject of the health claims is policosanols from sugar cane wax.

Sugar cane-derived policosanols contain 66-67 % octacosanol (28-C), 12-14 % triacosanol (30-C), 7-8 % hexacosanol (26-C) and 11-15 % of other carbon alcohols, including tetracosanol (24-C), heptacosanol (27-C), nonacosanol (29-C), dotriacontanol (32-C) and tetratriacontanol (34-C) (Natural Medicines Comprehensive Database, 2006).

The Panel considers that the food constituent, policosanols from sugar cane wax, which is the subject of the health claims, is sufficiently characterised.

2. Relevance of the claimed effect to human health

2.1. Maintenance of normal blood LDL-cholesterol concentrations (ID 1747, 1748, 1864, 1951, 1954, 4693)

The claimed effects are "cholesterol", "support for healthy blood lipid levels", and "cardiovascular system". The Panel assumes that the target population is the general population.

In the context of the proposed wordings, the Panel assumes that the claimed effects refer to the maintenance of normal LDL-cholesterol concentrations.

[4] Regulation (EC) No 1924/2006 of the European Parliament and of the Council of 20 December 2006 on nutrition and health claims made on foods. OJ L 404, 30.12.2006, p. 9–25.

[5] EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA), 2011. General guidance for stakeholders on the evaluation of Article 13.1, 13.5 and 14 health claims. EFSA Journal, 9(4):2135, 24 pp.

Low-density lipoproteins (LDL) carry cholesterol from the liver to peripheral tissues, including the arteries. Elevated LDL-cholesterol, by convention >160 mg/dL (>4.1 mmol/L), may compromise the normal structure and function of the arteries.

The Panel considers that maintenance of normal blood LDL-cholesterol concentrations is a beneficial physiological effect.

2.2. Maintenance of normal blood HDL-cholesterol concentrations (ID 1747, 1748, 1864, 1951, 1954, 4693)

The claimed effects are "cholesterol", "support for healthy blood lipid levels", and "cardiovascular system". The Panel assumes that the target population is the general population.

In the context of the proposed wordings, the Panel assumes that the claimed effects refer to the maintenance of normal HDL-cholesterol concentrations.

High-density lipoproteins (HDL) act as cholesterol scavengers, and are involved in the reverse transport of cholesterol in the body (from peripheral tissues back to the liver). Conversely, low-density lipoproteins (LDL) carry cholesterol from the liver to peripheral tissues, including the arteries.

The Panel considers that maintenance of normal HDL-cholesterol concentrations (without increasing LDL-cholesterol concentrations) is a beneficial physiological effect.

3. Scientific substantiation of the claimed effect

3.1. Maintenance of normal blood LDL-cholesterol concentrations (ID 1747, 1748, 1864, 1951, 1954, 4693)

Some of the references provided for the scientific substantiation of the claim reported on health outcomes (e.g. platelet aggregation, intermittent claudication, *in vitro* LDL oxidation) other than changes in the blood lipid profile. Also, narrative reviews on the effects of policosanols on blood lipids were provided. The Panel considers that no conclusions can be drawn from these references for the scientific substantiation of the claim.

Fourteen references reported on 13 human intervention studies which investigated the effects of policosanol consumption on blood lipids. Two references reported on the same study (Kassis and Jones, 2006, 2008).

All of these studies except four (Berthold et al., 2006; Francini-Pesenti et al., 2008a; 2008b; Kassis and Jones, 2006, 2008) were conducted in Cuba in Cuban subjects by a single research team using policosanols from Cuban sugar cane wax produced by a single company. In these placebo-controlled, double-blind, randomised controlled trials, the efficacy of policosanols on blood lipids was studied in groups of hypercholesterolaemic subjects (non-insulin dependent diabetics, post-menopausal women, elderly, subjects at high risk of coronary heart disease) (Batista et al., 1996; Canetti et al., 1997; Castaño et al., 1995; Castaño et al., 1999; 2001; 2005; Crespo et al., 1999; Pons et al., 1994), and in one group of healthy subjects (Hernández et al., 1992). Sample sizes varied between 22 and 244 subjects, doses between 5 and 20 mg policosanols per day, and treatment periods between four weeks and 24 months. In one study using 10 mg/day policosanols, subjects (n=85) were followed up for five years (open three-year follow up after participation in a two-year controlled intervention trial). Efficacy was found to be maintained during this long-term follow up (Canetti et al., 1997). In these studies the (statistically significant) reductions reported for total and LDL-cholesterol concentrations

varied between 17-21 % and 21-29 %, respectively. Similar results were reported in a meta-analysis of randomised controlled trials in which these studies were included (Chen et al., 2005).

A multicentre (lipid outpatient clinics and general practitioners in Germany), randomised, double-blind, placebo-controlled, parallel group intervention trial was designed to corroborate the reported lipid-lowering effects of policosanols from Cuban sugar cane wax. The policosanols used in this study were provided by the same company as in the studies described above (Berthold et al., 2006). A total of 143 subjects with hypercholesterolaemia or combined hyperlipidaemia (LDL-cholesterol concentrations >3.88 mmol/L) and either no or one risk factor for cardiovascular disease (CVD) other than known coronary heart disease (CHD), or baseline LDL-cholesterol concentrations between 3.88 and 4.89 mmol/L and two or more risk factors for CVD, were randomised to one of the five following groups after an open-label six-week placebo and diet run-in phase: 10 mg/day (n=28), 20 mg/day (n=27), 40 mg/day (n=27), or 80 mg/day (n=32) of policosanols, or placebo (n=29). The intervention phase lasted 12 weeks. Sample size was calculated based on the percentage change of LDL-cholesterol concentrations from baseline, a level of significance of $p<0.025$ (1-sided), and a power of 80 %. It was expected that the active treatment would result in an LDL-cholesterol decrease of at least 10 % (with an SD of 11 %) compared with placebo. To achieve the calculated power, 20 patients per intervention group were needed. Results were analysed on an intention-to-treat basis. A total of 129 subjects completed the trial. In none of the five treatment groups did LDL-cholesterol concentrations decrease more than 10 % from baseline. No statistically significant differences between any of the policosanol groups and placebo were observed. There was no significant dose-response relationship between policosanol intake and changes in LDL-cholesterol concentrations. No statistically significant differences between any of the policosanol groups and placebo were observed for any of the secondary outcome measures, i.e. total cholesterol, HDL-cholesterol, VLDL-(very low density lipoprotein) cholesterol, triglycerides, lipoprotein(a), and ratio of total or LDL- to HDL-cholesterol. The Panel notes that this study does not show an effect of policosanols at doses from 10 to 80 mg/day on LDL-cholesterol concentrations.

In a double-blind, randomised, placebo-controlled study, 68 subjects with LDL-cholesterol concentrations between 160 and 250 mg/dL followed a normocaloric diet according to the National Cholesterol Education Program Adult Treatment Panel III for three months, and thereafter were randomised to consume either two tablets of policosanols (each tablet containing 10 mg policosanols from Cuban sugar cane wax) or placebo (calcium phosphate, calcium carbonate and magnesium stearate) after dinner for eight weeks, while following their usual lifestyle and a normocaloric diet (Francini-Pesenti et al., 2008a). It was estimated that to achieve 80 % power to detect a reduction in serum LDL-cholesterol concentrations of 20 % at a 2-sided significance level of 5 %, 30 subjects per group would be required. Thirty-one subjects (16 males, mean age 52±6 years) in the policosanol group and 32 subjects (14 males, mean age 54±7 years) in the placebo group completed the study. Reasons for withdrawal were reported and analyses were provided on completers only. No statistically significant changes in total or LDL-cholesterol concentrations (-2.8 mg/dL *vs*. -2.0 mg/dL, p=0.34; -0.9 mg/dL *vs*. -0.3 mg/dL, p=0.89, respectively) nor in HDL-cholesterol concentrations (+1.9 mg/dL *vs*. +2.9 mg/dL, p=0.66) were observed between the policosanol and the placebo groups. The Panel notes that this study does not show an effect of policosanol consumption at doses of 20 mg/day on blood LDL-cholesterol concentrations.

The same group conducted another double-blind, randomised, placebo-controlled study in which 70 subjects with LDL-cholesterol concentrations between 4.0 and 5.2 mmol/L who had reduced their LDL-cholesterol concentrations more than 0.3 mmol/L by following a normocaloric diet according to the National Cholesterol Education Program Adult Treatment Panel III were randomised to consume one tablet daily containing either 10 mg of policosanols from Cuban sugar cane wax or placebo (calcium phosphate, calcium carbonate and magnesium stearate) after dinner for eight weeks, while following their usual lifestyle and a normocaloric diet (Francini-Pesenti et al., 2008b). Power calculations were performed as described in the study by Francini-Pesenti et al. (2008a). Thirty-three

subjects (11 males, mean age 48±5 years) in the policosanol group and 31 subjects (14 males, mean age 53±6 years) in the placebo group completed the study. Reasons for withdrawal were reported and analyses were provided on completers only. No statistically significant changes in total or LDL-cholesterol concentrations (-0.01 mmol/L *vs*. -0.05 mmol/L, p=0.69; -0.01 mmol/L *vs*. +0.11 mmol/L, p=0.94 respectively), nor in HDL-cholesterol concentrations (+0.07 mmol/L *vs*. +0.03 mmol/L, p=0.66) were observed between the policosanol and the placebo groups. The Panel notes that this study does not show an effect of policosanol consumption at doses of 10 mg/day on blood cholesterol concentrations.

In a double-blind, placebo-controlled, cross-over study by Kassis and Jones (2006, 2008) 22 subjects with LDL-cholesterol concentrations between 3.0 and 5.0 mmol/L were recruited to receive either 10 g margarine containing 10 mg policosanols derived from sugar cane wax or a placebo margarine for 28 days each, with a 28-day wash-out period in between. A sample size of 21 was calculated to provide an 80 % probability of detecting a difference of 20 % between groups in the parameters measured, using a coefficient of variation of 15-20 %. Statistical significance was set at $p<0.05$. Twenty-one subjects (12 males, mean age 57.8±2.1 years) completed the study. On day 25 of each study period, subjects were administered 10 g of margarine providing 75 mg of stable isotope-labelled cholesterol in order to assess cholesterol absorption. On day 28 of each study period, a dose of deuterium oxide was given to subjects in order to determine the amounts of cholesterol biosynthesis by measuring deuterium incorporation into red blood cell membrane free cholesterol over 24 hours. No statistically significant changes were observed in total or LDL-cholesterol concentrations (+1.8±3.0 % *vs*. -4.0±3.0 %, p=0.18; +4.5±4.0 % *vs*. -1.6±4.0 %, p=0.28, respectively), nor in HDL-cholesterol concentrations (-2.7±3.0 % *vs*. -7.4±3.0 %, p=0.19) between the intervention and placebo periods. No statistically significant differences in the area under the curve (AUC) for cholesterol absorption or in the fractional rate of cholesterol synthesis were found between the intervention and the control periods. The Panel notes that this study does not show an effect of policosanol consumption at doses of 10 mg/day on blood cholesterol concentrations, on cholesterol absorption, or on the rate of endogenous cholesterol synthesis.

The Panel notes that although the majority of the studies conducted in Cuban subjects reported significant reductions in total and LDL-cholesterol concentrations between 17-21 % and 21-29 % respectively following consumption of policosanols from sugar cane wax at doses between 5 and 20 mg/day, no effect on total or LDL-cholesterol concentrations was found in human intervention studies conducted in other parts of the world at doses ranging from 10 to 80 mg/day.

The Panel also notes that no effect of policosanols from sugar cane wax on cholesterol absorption or on the rate of endogenous cholesterol synthesis has been observed *in vivo* in humans (Kassis and Jones, 2006, 2008), and that no evidence for a mechanism by which policosanols could exert the claimed effect has been provided.

In weighing the evidence, the Panel took into account that the results from human intervention studies which assessed the effects of policosanols from sugar cane wax on total and LDL-cholesterol concentrations are inconsistent, and that no evidence for a mechanism by which policosanols from sugar cane wax could exert the claimed effect has been provided.

The Panel concludes that a cause and effect relationship has not been established between the consumption of policosanols from sugar cane wax and maintenance of normal blood LDL-cholesterol concentrations.

3.2. Maintenance of normal blood HDL-cholesterol concentrations (ID 1747, 1748, 1864, 1951, 1954, 4693)

The same human intervention studies described in section 3.1 also reported on the effects of consumption of policosanol from sugar cane wax on HDL-cholesterol concentrations. Whereas the nine human intervention studies conducted in Cuban subjects generally reported a statistically significant increase in HDL-cholesterol concentrations which varied between 8 and 15 % (Batista et al., 1996; Canetti et al., 1997; Castaño et al., 1995; Castaño et al., 1999; 2001; 2005; Crespo et al., 1999; Hernández et al., 1992; Pons et al., 1994), no significant effect was observed in the four studies conducted in other parts of the world (Berthold et al., 2006; Francini-Pesenti et al., 2008a; 2008b; Kassis and Jones, 2006, 2008), and no evidence for a mechanism by which policosanols from sugar cane wax could exert the claimed effect has been provided.

In weighing the evidence, the Panel took into account that the results from human intervention studies which assessed the effects of policosanols from sugar cane wax on HDL-cholesterol concentrations are inconsistent, and that no evidence for a mechanism by which policosanols from sugar cane wax could exert the claimed effect has been provided.

The Panel concludes that a cause and effect relationship has not been established between the consumption of policosanols from sugar cane wax and maintenance of normal blood HDL-cholesterol concentrations.

CONCLUSIONS

On the basis of the data presented, the Panel concludes that:

- The food constituent, policosanols from sugar cane wax, which is the subject of the health claims, is sufficiently characterised.

Maintenance of normal blood LDL-cholesterol concentrations (ID 1747, 1748, 1864, 1951, 1954, 4693)

- The claimed effects are “cholesterol”, “support for healthy blood lipid levels”, and “cardiovascular system”. The target population is assumed to be the general population. In the context of the proposed wordings, it is assumed that the claimed effects refer to the maintenance of normal LDL-cholesterol concentrations. Maintenance of normal blood LDL-cholesterol concentrations is a beneficial physiological effect.

- A cause and effect relationship has not been established between the consumption of policosanols from sugar cane wax and maintenance of normal blood LDL-cholesterol concentrations.

Maintenance of normal blood HDL-cholesterol concentrations (ID 1747, 1748, 1864, 1951, 1954, 4693)

- The claimed effects are “cholesterol”, “support for healthy blood lipid levels”, and “cardiovascular system”. The Panel assumes that the target population is the general population. In the context of the proposed wordings, it is assumed that the claimed effects refer to the maintenance of normal HDL-cholesterol concentrations. Maintenance of normal HDL-cholesterol concentrations (without increasing LDL-cholesterol concentrations) is a beneficial physiological effect.

- A cause and effect relationship has not been established between the consumption of policosanols from sugar cane wax and maintenance of normal blood HDL-cholesterol concentrations.

DOCUMENTATION PROVIDED TO EFSA

Health claims pursuant to Article 13 of Regulation (EC) No 1924/2006 (No: EFSA-Q-2008-2480, EFSA-Q-2008-2481, EFSA-Q-2008-2597, EFSA-Q-2008-2684, EFSA-Q-2008-2687, EFSA-Q-2010-00646). The scientific substantiation is based on the information provided by the Member States in the consolidated list of Article 13 health claims and references that EFSA has received from Member States or directly from stakeholders.

The full list of supporting references as provided to EFSA is available on: http://www.efsa.europa.eu/panels/nda/claims/article13.htm.

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APPENDICES

APPENDIX A

BACKGROUND AND TERMS OF REFERENCE AS PROVIDED BY THE EUROPEAN COMMISSION

The Regulation 1924/2006 on nutrition and health claims made on foods[6] (hereinafter "the Regulation") entered into force on 19th January 2007.

Article 13 of the Regulation foresees that the Commission shall adopt a Community list of permitted health claims other than those referring to the reduction of disease risk and to children's development and health. This Community list shall be adopted through the Regulatory Committee procedure and following consultation of the European Food Safety Authority (EFSA).

Health claims are defined as "any claim that states, suggests or implies that a relationship exists between a food category, a food or one of its constituents and health".

In accordance with Article 13 (1) health claims other than those referring to the reduction of disease risk and to children's development and health are health claims describing or referring to:

a) the role of a nutrient or other substance in growth, development and the functions of the body; or

b) psychological and behavioural functions; or

c) without prejudice to Directive 96/8/EC, slimming or weight-control or a reduction in the sense of hunger or an increase in the sense of satiety or to the reduction of the available energy from the diet.

To be included in the Community list of permitted health claims, the claims shall be:

(i) based on generally accepted scientific evidence; and

(ii) well understood by the average consumer.

Member States provided the Commission with lists of claims as referred to in Article 13 (1) by 31 January 2008 accompanied by the conditions applying to them and by references to the relevant scientific justification. These lists have been consolidated into the list which forms the basis for the EFSA consultation in accordance with Article 13 (3).

ISSUES THAT NEED TO BE CONSIDERED

IMPORTANCE AND PERTINENCE OF THE FOOD[7]

Foods are commonly involved in many different functions[8] of the body, and for one single food many health claims may therefore be scientifically true. Therefore, the relative importance of food e.g. nutrients in relation to other nutrients for the expressed beneficial effect should be considered: for functions affected by a large number of dietary factors it should be considered whether a reference to a single food is scientifically pertinent.

[6] OJ L12, 18/01/2007

[7] The term 'food' when used in this Terms of Reference refers to a food constituent, the food or the food category.

[8] The term 'function' when used in this Terms of Reference refers to health claims in Article 13(1)(a), (b) and (c).

It should also be considered if the information on the characteristics of the food contains aspects pertinent to the beneficial effect.

SUBSTANTIATION OF CLAIMS BY GENERALLY ACCEPTABLE SCIENTIFIC EVIDENCE

Scientific substantiation is the main aspect to be taken into account to authorise health claims. Claims should be scientifically substantiated by taking into account the totality of the available scientific data, and by weighing the evidence, and shall demonstrate the extent to which:

(a) the claimed effect of the food is beneficial for human health,

(b) a cause and effect relationship is established between consumption of the food and the claimed effect in humans (such as: the strength, consistency, specificity, dose-response, and biological plausibility of the relationship),

(c) the quantity of the food and pattern of consumption required to obtain the claimed effect could reasonably be achieved as part of a balanced diet,

(d) the specific study group(s) in which the evidence was obtained is representative of the target population for which the claim is intended.

EFSA has mentioned in its scientific and technical guidance for the preparation and presentation of the application for authorisation of health claims consistent criteria for the potential sources of scientific data. Such sources may not be available for all health claims. Nevertheless it will be relevant and important that EFSA comments on the availability and quality of such data in order to allow the regulator to judge and make a risk management decision about the acceptability of health claims included in the submitted list.

The scientific evidence about the role of a food on a nutritional or physiological function is not enough to justify the claim. The beneficial effect of the dietary intake has also to be demonstrated. Moreover, the beneficial effect should be significant i.e. satisfactorily demonstrate to beneficially affect identified functions in the body in a way which is relevant to health. Although an appreciation of the beneficial effect in relation to the nutritional status of the European population may be of interest, the presence or absence of the actual need for a nutrient or other substance with nutritional or physiological effect for that population should not, however, condition such considerations.

Different types of effects can be claimed. Claims referring to the maintenance of a function may be distinct from claims referring to the improvement of a function. EFSA may wish to comment whether such different claims comply with the criteria laid down in the Regulation.

WORDING OF HEALTH CLAIMS

Scientific substantiation of health claims is the main aspect on which EFSA's opinion is requested. However, the wording of health claims should also be commented by EFSA in its opinion.

There is potentially a plethora of expressions that may be used to convey the relationship between the food and the function. This may be due to commercial practices, consumer perception and linguistic or cultural differences across the EU. Nevertheless, the wording used to make health claims should be truthful, clear, reliable and useful to the consumer in choosing a healthy diet.

In addition to fulfilling the general principles and conditions of the Regulation laid down in Article 3 and 5, Article 13(1)(a) stipulates that health claims shall describe or refer to "the role of a nutrient or other substance in growth, development and the functions of the body". Therefore, the requirement to

describe or refer to the 'role' of a nutrient or substance in growth, development and the functions of the body should be carefully considered.

The specificity of the wording is very important. Health claims such as "Substance X supports the function of the joints" may not sufficiently do so, whereas a claim such as "Substance X helps maintain the flexibility of the joints" would. In the first example of a claim it is unclear which of the various functions of the joints is described or referred to contrary to the latter example which specifies this by using the word "flexibility".

The clarity of the wording is very important. The guiding principle should be that the description or reference to the role of the nutrient or other substance shall be clear and unambiguous and therefore be specified to the extent possible i.e. descriptive words/ terms which can have multiple meanings should be avoided. To this end, wordings like "strengthens your natural defences" or "contain antioxidants" should be considered as well as "may" or "might" as opposed to words like "contributes", "aids" or "helps".

In addition, for functions affected by a large number of dietary factors it should be considered whether wordings such as "indispensable", "necessary", "essential" and "important" reflects the strength of the scientific evidence.

Similar alternative wordings as mentioned above are used for claims relating to different relationships between the various foods and health. It is not the intention of the regulator to adopt a detailed and rigid list of claims where all possible wordings for the different claims are approved. Therefore, it is not required that EFSA comments on each individual wording for each claim unless the wording is strictly pertinent to a specific claim. It would be appreciated though that EFSA may consider and comment generally on such elements relating to wording to ensure the compliance with the criteria laid down in the Regulation.

In doing so the explanation provided for in recital 16 of the Regulation on the notion of the average consumer should be recalled. In addition, such assessment should take into account the particular perspective and/or knowledge in the target group of the claim, if such is indicated or implied.

TERMS OF REFERENCE

HEALTH CLAIMS OTHER THAN THOSE REFERRING TO THE REDUCTION OF DISEASE RISK AND TO CHILDREN'S DEVELOPMENT AND HEALTH

EFSA should in particular consider, and provide advice on the following aspects:

- Whether adequate information is provided on the characteristics of the food pertinent to the beneficial effect.
- Whether the beneficial effect of the food on the function is substantiated by generally accepted scientific evidence by taking into account the totality of the available scientific data, and by weighing the evidence. In this context EFSA is invited to comment on the nature and quality of the totality of the evidence provided according to consistent criteria.
- The specific importance of the food for the claimed effect. For functions affected by a large number of dietary factors whether a reference to a single food is scientifically pertinent.

In addition, EFSA should consider the claimed effect on the function, and provide advice on the extent to which:

- the claimed effect of the food in the identified function is beneficial.
- a cause and effect relationship has been established between consumption of the food and the claimed effect in humans and whether the magnitude of the effect is related to the quantity

consumed.

- where appropriate, the effect on the function is significant in relation to the quantity of the food proposed to be consumed and if this quantity could reasonably be consumed as part of a balanced diet.
- the specific study group(s) in which the evidence was obtained is representative of the target population for which the claim is intended.
- the wordings used to express the claimed effect reflect the scientific evidence and complies with the criteria laid down in the Regulation.

When considering these elements EFSA should also provide advice, when appropriate:

- on the appropriate application of Article 10 (2) (c) and (d) in the Regulation, which provides for additional labelling requirements addressed to persons who should avoid using the food; and/or warnings for products that are likely to present a health risk if consumed to excess.

APPENDIX B

EFSA DISCLAIMER

The present opinion does not constitute, and cannot be construed as, an authorisation to the marketing of the food/food constituent, a positive assessment of its safety, nor a decision on whether the food/food constituent is, or is not, classified as foodstuffs. It should be noted that such an assessment is not foreseen in the framework of Regulation (EC) No 1924/2006.

It should also be highlighted that the scope, the proposed wordings of the claims and the conditions of use as proposed in the Consolidated List may be subject to changes, pending the outcome of the authorisation procedure foreseen in Article 13(3) of Regulation (EC) No 1924/2006.

APPENDIX C

Table 1. Main entry health claims related to policosanols, including conditions of use from similar claims, as proposed in the Consolidated List.

ID	Food or Food constituent	Health Relationship	Proposed wording
1747	Policosanol / Blend of aliphatic alcohols - consisting primarily of 1-Octacosanol, 1-Triacontanol, 1-Tetracosanol and 1-Hexacosanol - from sugar cane (Saccharum officinarum).	Cholesterol	Policosanol helps to maintain healthy cholesterol levels / contributes to good LDL cholesterol level / contributes to good HDL cholesterol level
	Conditions of use - 5-40 mg/day		
ID	**Food or Food constituent**	**Health Relationship**	**Proposed wording**
1748	Policosanol [from sugarcane wax (Saccarum officinarum)]	Support for Healthy Blood Lipid Levels	Support for Healthy Blood Lipid Levels/ Natural Blood Lipid Support/ Policosanol supports healthy lipid metabolism/ Policosanol may promote LDL binding, uptake, and degradation/ Policosanol may help maintain healthy blood pressure levels already within normal range
	Conditions of use - The recommended daily dosage: 5 to 20 mg/day		
ID	**Food or Food constituent**	**Health Relationship**	**Proposed wording**
1864	Sugar cane extract	Cardiovascular system	Increases beneficial HDL cholesterol./ Beneficial for the heart and blood vessels.
	Conditions of use - Food supplement containing 10-20 mg of sugar cane extract with policosanol in the daily dose.		
	No clarification provided by Member States		
ID	**Food or Food constituent**	**Health Relationship**	**Proposed wording**
1951	Policosanols	Cholesterol	Helps to decrease cholesterol biosynthesis, which is higher during the night./ Helps to decrease hepatic production of cholesterol, more elevated at night./ Helps to control blood levels of cholesterol./ Helps to improve cholesterol profile.
	Conditions of use - At least 5 mg per day		

ID	Food or Food constituent	Health Relationship	Proposed wording
1954	Policosanols	Cholesterol	Helps to decrease cholesterol biosynthesis, which is higher during the night./ Helps to decrease hepatic production of cholesterol, more elevated at night. Helps to control blood levels of cholesterol./ Helps to improve cholesterol profile.
	Conditions of use - At least 5 mg per day		
ID	**Food or Food constituent**	**Health Relationship**	**Proposed wording**
4693	POLICOSANOL	Cardiovascular system benefit	Reducing cholesterol levels
	Conditions of use - Oral administration, capsules or tablets		

GLOSSARY AND ABBREVIATIONS

AUC	Area under the curve
CVD	Cardiovascular disease
CHD	Coronary heart disease
HDL	High-density lipoproteins
LDL	Low-density lipoproteins
VLDL	Very low-density lipoproteins